

SECTION 5

SCREENING VALUES FOR TARGET ANALYTES

For the purpose of this guidance document, screening values are defined as concentrations of target analytes in fish or shellfish tissue that are of potential public health concern and that are used as standards against which levels of contamination in similar tissue collected from the ambient environment can be compared. Exceedance of these SVs should be taken as an indication that more intensive site-specific monitoring and/or evaluation of human health risk should be conducted.

The EPA-recommended risk-based method for developing SVs (U.S. EPA, 1989d) is described in this section. This method is considered to be appropriate for protecting the health of fish and shellfish consumers for the following reasons (Reinert et al., 1991):

- It gives full priority to protection of public health.
- It provides a direct link between fish consumption rate and risk levels (i.e., between dose and response).
- It generally leads to conservative estimates of increased risk.
- It is designed for protection of consumers of locally caught fish and shellfish, including susceptible subpopulations such as sport and subsistence fishermen who are at potentially greater risk than the general adult population because they tend to consume greater quantities of fish and because they frequently fish the same sites repeatedly.

At this time, the EPA Office of Water is recommending use of this method because it is the basis for developing current water quality criteria and was the approach used in the National Study of Chemical Residues in Fish (U.S. EPA, 1992c, 1992d). EPA recognizes that there are many other approaches and models currently in use. Further discussion of the EPA Office of Water risk-based approach, including a detailed description of the four steps involved in risk assessment (hazard identification, dose-response assessment, exposure assessment, and risk characterization) will be discussed in greater detail in the second guidance document in this series.

5.1 GENERAL EQUATIONS FOR CALCULATING SCREENING VALUES

Risk-based SVs are derived from the general model for calculating the effective ingested dose of a chemical m (E_m) (U.S. EPA, 1989d):

$$E_m = (C_m \cdot CR \cdot X_m) / BW \quad (5-1)$$

where

E_m = Effective ingested dose of chemical m in the population of concern averaged over a 70-yr lifetime (mg/kg/d)

C_m = Concentration of chemical m in the edible portion of the species of interest (mg/kg; ppm)

CR = Mean daily consumption rate of the species of interest by the general population or subpopulation of concern averaged over a 70-yr lifetime (kg/d)

X_m = Relative absorption coefficient, or the ratio of human absorption efficiency to test animal absorption efficiency for chemical m (dimensionless)

BW = Mean body weight of the general population or subpopulation of concern (kg).

Using this model, the SV for the chemical m (SV_m) is equal to C_m when the appropriate measure of toxicologic potency of the chemical m (P_m) is substituted for E_m . Rearrangement of Equation (5-1), with these substitutions, gives

$$SV_m = (P_m \cdot BW) / (CR \cdot X_m) \quad (5-2)$$

where

P_m = Toxicologic potency for chemical m ; the effective ingested dose of chemical m associated with a specified level of health risk as estimated from dose-response studies; **dose-response variable**.

In most instances, relative absorption coefficients (X_m) are assumed to be 1.0 (i.e., human absorption efficiency is assumed to be equal to that of the test animal), so that

$$SV_m = (P_m \cdot BW) / CR \quad (5-3)$$

However, if X_m is known, Equation (5-2) should be used to calculate SV_m .

Dose-response variables for noncarcinogens and carcinogens are defined in Sections 5.1.1 and 5.1.2, respectively. These variables are based on an assessment of the occurrence of a critical toxic or carcinogenic effect via a specific route of exposure (i.e., ingestion, inhalation, dermal contact). Oral dose-

response variables for the recommended target analytes are given in Appendix E. Because of the fundamental differences between the noncarcinogenic and carcinogenic dose-response variables used in the EPA risk-based method, SVs must be calculated separately for noncarcinogens and potential carcinogens as shown in the following subsections.

5.1.1 Noncarcinogens

The dose-response variable for noncarcinogens is the **Reference Dose (RfD)**. The RfD is an estimate of a daily exposure to the human population (including sensitive subpopulations) that is likely to be without appreciable risk of deleterious effects during a lifetime. The RfD is derived by applying uncertainty or modifying factors to a subthreshold dose (i.e., LOAEL if the NOAEL is indeterminate) observed in chronic animal bioassays. These uncertainty or modifying factors range from 1 to 10 for each factor and are used to account for uncertainties in:

- Sensitivity differences among human subpopulations
- Interspecies extrapolation from animal data to humans
- Short-term to lifetime exposure extrapolation from less than chronic results on animals to humans when no long-term human data are available
- Deriving an RfD from a LOAEL instead of a NOAEL
- Incomplete or inadequate toxicity or pharmacokinetic databases.

The uncertainty (UF) and modifying (MF) factors are multiplied to obtain a final UF•MF value. This factor is divided into the NOAEL or LOAEL to derive the RfD (Barnes and Dawson, 1988; U.S. EPA, 1989d).

The following equation should be used to calculate SVs for noncarcinogens:

$$SV_n = (RfD \cdot BW)/CR \quad (5-4)$$

where

SV_n = Screening value for a noncarcinogen (mg/kg; ppm)
RfD = Oral reference dose (mg/kg/d)

and BW and CR are defined as in Equation (5-1).

5.1.2 Carcinogens

According to *The Risk Assessment Guidelines of 1986* (U.S. EPA, 1987f), the default model for low-dose extrapolation of carcinogens is a version (GLOBAL 86) of the linearized multistage no-threshold model developed by Crump et al. (1976). This extrapolation procedure provides an upper 95 percent bound risk estimate (referred to as a $q1^*$), which is considered by some to be a conservative estimate of cancer risk. Other extrapolation procedures may be used when justified by the data.

Screening values for carcinogens are derived from: (1) a carcinogenicity potency factor or **slope factor (SF)**, which is generally an upper bound risk estimate; and (2) a **risk level (RL)**, an assigned level of maximum acceptable individual lifetime risk (e.g., $RL = 10^{-5}$ for a level of risk not to exceed one excess case of cancer per 100,000 individuals exposed over a 70-yr lifetime) (U.S. EPA, 1989d).

The following equation should be used to calculate SVs for carcinogens:

$$SV_c = [(RL / SF) \cdot BW] / CR \quad (5-5)$$

where

SV_c = Screening value for a carcinogen (mg/kg; ppm)
RL = Maximum acceptable risk level (dimensionless)
SF = Oral slope factor (mg/kg/d)⁻¹

and BW and CR are defined as in Equation (5-1).

5.1.3 Recommended Values for Variables in Screening Value Equations

The recommended values in this section for variables used in Equations (5-4) and (5-5) to calculate SVs are based upon assumptions for the general adult population. For risk management purposes (e.g., to direct limited resources toward protection of sensitive subpopulations), States may choose to use values for consumption rate (CR), body weight (BW), and risk level (RL) different from those recommended in this section.

5.1.3.1 Dose-Response Variables—

EPA has developed oral RfDs and/or SFs for all of the recommended target analytes in Section 4 (see Appendix E). These are maintained in the EPA Integrated Risk Information System (IRIS, 1992), an electronic database containing health risk and EPA regulatory information on approximately 400 different chemicals. The IRIS RfDs and SFs are reviewed regularly and updated as necessary when new or more reliable information on the toxic or carcinogenic potency of chemicals becomes available.

When IRIS values for oral RfDs and SFs are available, they should be used to calculate SVs for target analytes from Equations (5-4) and (5-5), respectively. It is important that the most current IRIS values for oral RfDs and SFs be used to calculate SVs for target analytes, unless otherwise recommended.

A summary description of IRIS and instructions for accessing information in IRIS are found in U.S. EPA (1989d). Additional information can be obtained from IRIS User Support (Tel: 513-569-7254). IRIS is also available on the National Institutes of Health (NIH) National Library of Medicine TOXNET system (Tel: 301-496-6531).

In cases where IRIS values for oral RfDs or SFs are not available for calculating SVs for target analytes, estimates of these variables should be derived from the most recent water quality criteria (U.S. EPA, 1992e) according to procedures described in U.S. EPA (1991a, p. IV-12), or from the most current Reference Dose List (U.S. EPA, 1993b) and the Classification List of Chemicals Evaluated for Carcinogenicity Potential (U.S. EPA 1992a) from the Office of Pesticide Programs Health Effects Division.

5.1.3.2 Body Weight (BW) and Consumption Rate (CR)—

Values for the variables BW and CR in Equations (5-4) and (5-5) are given in Table 5-1 for the general adult population and various subpopulations. In this document, the EPA Office of Water used a BW = 70 kg and a CR = 6.5 g/d to calculate SVs for the general adult population. **Note:** The 6.5-g/d CR value that is used to establish water quality criteria is currently under review by the EPA Office of Water. This CR, which represents a consumption rate for the average fish consumer in the general adult population (45 FR 231, Part V), may not be appropriate for sport and subsistence fishermen who generally consume larger quantities of fish and shellfish (U.S. EPA, 1990a).

With respect to consumption rates, EPA recommends that States always evaluate any type of consumption pattern they believe could reasonably be occurring at a site. Evaluating additional consumption rates only involves calculating additional SVs and does not add to sampling or analytical costs.

The EPA has published detailed guidance on exposure factors (U.S. EPA, 1990a). In addition, EPA has published a review and analysis of survey methods that can be used by States to determine fish and shellfish consumption rates of local populations (U.S. EPA, 1992b). States should consult these documents to ensure that appropriate values are selected to calculate SVs for site-specific exposure scenarios.

5.1.3.3 Risk Level (RL)—

The EPA Office of Water recommends that an RL of 10^{-5} be used to calculate screening values for the general adult population. However, States may choose to use an appropriate RL value typically ranging from 10^{-4} to 10^{-7} . This is the range of risk levels employed in various U.S. EPA programs. Selection of the appropriate RL is a risk management decision that is made by the State.

5.2 RECOMMENDED SCREENING VALUES FOR TARGET ANALYTES

Recommended target analyte SVs, and the dose-response variables used to calculate them, are given in Table 5-2. These SVs were calculated from Equations (5-4) or (5-5) using the following values for BW, CR, and RL and the most current IRIS values for oral RfDs and SFs (IRIS, 1992) unless otherwise noted:

Table 5-1. Recommended Values for Mean Body Weights (BW) and Fish Consumption Rates (CRs) for Selected Subpopulations

Variable	Recommended value	Subpopulation
BW	70 kg	All adults (U.S. EPA, 1990a)
	78 kg	Adult males (U.S. EPA, 1985b, 1990a)
	65 kg	Adult females (U.S. EPA, 1985b, 1990a)
	12 kg	Children <3 yr (U.S. EPA, 1985b, 1990a)
	17 kg	Children 3 to <6 yr (U.S. EPA, 1985b, 1990a)
	25 kg	Children 6 to <9 yr (U.S. EPA, 1985b, 1990a)
	36 kg	Children 9 to <12 yr (U.S. EPA, 1985b, 1990a)
	51 kg	Children 12 to <15 yr (U.S. EPA, 1985b, 1990a)
	61 kg	Children 15 to <18 yr (U.S. EPA, 1985b, 1990a)
CR^a	6.5 g/d (0.0065 kg/d)	Estimate of the average consumption of fish and shellfish from estuarine and fresh waters by the general U.S. population (45 FR 231, Part V)
	14 g/d (0.014 kg/d)	Estimate of the average consumption of fish and shellfish from marine, estuarine, and fresh waters by the general U.S. population (45 FR 231, Part V)
	15 g/d (0.015 kg/d)	Estimate of the average consumption of fish from the Great Lakes by the 95th percentile of the regional population (fishermen and nonfishermen) (U.S. EPA, 1992e)
	30 g/d (0.030 kg/d)	Estimate of the average consumption of fish and shellfish from marine, estuarine, and fresh waters by the 50th percentile of recreational fishermen (U.S. EPA, 1990a)
	140 g/d (0.140 kg/d)	Estimate of the average consumption of fish and shellfish from marine, estuarine, and fresh waters by the 90th percentile of recreational fishermen (i.e., subsistence fishermen) (U.S. EPA, 1990a)

^a These are recommended consumption rates only. **Note:** EPA is currently evaluating the use of 6.5 g/d, 30 g/d, and 140 g/d as estimates of consumption rates for the general population, the 50th percentile of recreational fishermen, and subsistence fishermen, respectively. When local consumption rate data are available for these populations, they should be used to calculate SVs for noncarcinogens and carcinogens, as described in Sections 5.1.1 and 5.1.2, respectively.

- **For noncarcinogens:**

BW = 70 kg, average adult body weight

CR = 6.5 g/d (0.0065 kg/d), estimate of average consumption of fish and shellfish from estuarine and fresh waters by the general adult population (45 FR 231, Part V).

- **For carcinogens:**

BW and CR, as above

RL = 10^{-5} , a risk level corresponding to one excess case of cancer per 100,000 individuals exposed over a 70-yr lifetime.

Where both oral RfD and SF values are available for a given target analyte SVs for, both noncarcinogenic and carcinogenic effects are listed in Table 5-2. Unless otherwise indicated, the lower of the two SVs should be used. EPA recommends that the SVs in the shaded boxes (Table 5-2) be used by States when making the decision to implement Tier 2 intensive monitoring. However, States may choose to adjust these SVs for specific target analytes for the protection of sensitive subpopulations (e.g., pregnant women, children, and recreational or subsistence fishermen). EPA recognizes that States may use higher CRs that are more appropriate for recreational and subsistence fishermen in calculating SVs for use in their jurisdictions rather than the 6.5-g/d CR for the general adult population used to calculate the SVs shown in Table 5-2.

Note: States should use the same SV (i.e., either for the general adult population or adjusted for other subpopulations) for a given target analyte for both screening and intensive studies. Therefore, it is critical that States clearly define their program objectives and accurately characterize the population or subpopulation(s) of concern in order to ensure that appropriate SVs are selected. If analytical methodology is not sensitive enough to reliably quantitate target analytes at or below selected SVs (see Section 8.2.2 and Table 8-4), program managers must determine appropriate fish consumption guidance based on lowest detectable concentrations or provide justification for adjusting SVs to values at or above achievable method detection limits. It should be emphasized that when SVs are below method detection limits, the failure to detect a target analyte cannot be assumed to indicate that there is no cause for concern for human health effects.

For noncarcinogens, adjusted SVs should be calculated from Equation (5-4) using appropriate alternative values of BW and/or CR. For carcinogens, adjusted SVs should be calculated from Equation (5-5) using an RL ranging from 10^{-4} to 10^{-7} and/or sufficiently protective alternative values of BW and CR. Examples of SVs calculated for selected subpopulations of concern and for RL values ranging from 10^{-4} to 10^{-7} are given in Table 5-3.

Table 5-2. Dose-Response Variables and Recommended Screening Values (SVs) for Target Analytes

Target analyte	Noncarcinogens	Carcinogens	SV ^a (ppm)	
	RfD ^b (mg/kg/d)	SF ^b (mg/kg/d) ⁻¹	Noncarcinogens	Carcinogens (RL=10 ⁻⁵)
Metals				
Arsenic (inorganic) ^c	3 x 10 ^{-4 d}	NA ^e	3	—
Cadmium	1 x 10 ⁻³	NA	10	—
Mercury ^f				
Developmental	6 x 10 ^{-5 g}	NA	0.6 ^d	—
Chronic systemic	3 x 10 ^{-4 h}	NA	3 ^h	—
Selenium ⁱ	5 x 10 ⁻³	NA	50	—
Tributyltin	3 x 10 ^{-5 d}	NA	0.3	—
Organochlorine Pesticides				
Total chlordane (sum of cis- and trans-chlordane, cis- and trans-nonachlor, and oxychlordane) ^j	6 x 10 ⁻⁵	1.3	0.6	0.08
Total DDT (sum of 4,4'- and 2,4'-isomers of DDT, DDE, and DDD) ^k	5 x 10 ⁻⁴	0.34	5	0.3
Dicofol	1 x 10 ^{-3 l}	NA	10	—
Dieldrin	5 x 10 ⁻⁵	16	0.6	7 x 10 ⁻³
Endosulfan (I and II)	6 x 10 ^{-3 m}	NA	60	—
Endrin	3 x 10 ⁻⁴	NA	3	—
Heptachlor epoxide	1.3 x 10 ⁻⁵	9.1	0.1	0.01
Hexachlorobenzene	8 x 10 ⁻⁴	1.6	9	0.07

See notes at end of table

(continued)

Table 5-2 (continued)

Target analyte	Noncarcinogens	Carcinogens	SV ^a (ppm)	
	RfD ^b (mg/kg/d)	SF ^b (mg/kg/d) ⁻¹	Noncarcinogens	Carcinogens (RL=10 ⁻⁵)
<u>Metals</u>				
Lindane (γ-hexachlorocyclohexane; γ-HCH)	3 x 10 ⁻⁴	1.3 ⁿ	3	0.08
Mirex	2 x 10 ⁻⁴	NA ^o	2	—
Toxaphene	2.5 x 10 ⁻⁴ ^{l,p}	1.1	3	0.1
<u>Organophosphate Pesticides</u>				
Chlorpyrifos	3 x 10 ⁻³	NA	30	—
Diazinon	9 x 10 ⁻⁵ ^l	NA	0.9	—
Disulfoton	4 x 10 ⁻⁵	NA	0.5	—
Ethion	5 x 10 ⁻⁴	NA	5	—
Terbufos	1.3 x 10 ⁻⁴ ^l	NA	1	—
<u>Chlorophenoxy Herbicides</u>				
Oxyfluorfen	3 x 10 ⁻³	1.3 x 10 ⁻¹	30	0.8
<u>PAHs</u>	NA	7.3 ^{d,q}	—	0.01
<u>PCBs</u>				
Total PCBs (sum of Aroclors)	2 x 10 ⁻⁵ ^{d,r}	7.7 ^s	0.2	0.01
<u>Dioxins/furans</u>^t	NA	1.56 x 10 ⁵	—	7 x 10⁻⁷

(continued)

Table 5-2 (continued)

NA = Not available in EPA's Integrated Risk Information System (IRIS, 1992).

PAH = Polycyclic aromatic hydrocarbon.

PCB = Polychlorinated biphenyl.

RfD = Oral reference dose (mg/kg/d).

RL = Risk level (dimensionless).

SF = Oral slope factor (mg/kg/d)⁻¹.

^a Except for mercury, screening values (SVs) are target analyte concentrations in fish tissue that equal exposure levels at either the RfD for noncarcinogens or the SF and an RL=10⁻⁵ for carcinogens, given average consumption rates (CRs) and body weights (BW) of 6.5 g/d and 70 kg, respectively, for the general adult population (U.S. EPA, 1989d). **Note:** These values have been determined by rounding the final calculated value to one significant figure. EPA believes that using more than one significant figure would imply a degree of precision that is not warranted given the large uncertainty factors generally used in deriving SVs. For target analytes with both carcinogenic and noncarcinogenic effects, the lower (more conservative) of the calculated SVs should be used. **Note:** Values in the shaded boxes are SVs recommended for use in State fish/shellfish consumption advisory programs for the general adult population. States may choose to use other SVs based on different CRs, BWs, and/or an RL ranging from 10⁻⁴ to 10⁻⁷.

^b Unless otherwise noted, values listed are the most current oral RfDs and SFs in EPA's IRIS (IRIS, 1992).

^c Total inorganic arsenic should be determined for comparison with the recommended SV.

^d From IRIS (1995).

^e The SF for inorganic arsenic is currently under review by the Agency. At this time, EPA does not have a cancer SF for inorganic arsenic to recommend for use in conducting fish consumption risk assessments.

^f Because most mercury in fish and shellfish tissue is present as methylmercury (NAS, 1991; Tollefson, 1989) and because of the relatively high cost of analyzing for methylmercury, it is recommended that total mercury be analyzed and the conservative assumption be made that all mercury is present as methylmercury. This approach is deemed to be most protective of human health and most cost-effective.

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Table 5-2 (continued)

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- ^g **Note:** The EPA has recently reevaluated the RfD for methylmercury, primarily because of concern about evidence that the fetus is at increased risk of adverse neurological effects from exposure to methylmercury (Marsh et al., 1987; Piotrowski and Inskip, 1981; NAS, 1991; WHO, 1976, 1990). On May 1, 1995, IRIS was updated to include an oral RfD of 1×10^{-4} mg/kg/d based on developmental neurological effects in human infants. An oral RfD of 3×10^{-4} mg/kg/d for chronic systemic effects of methylmercury among the general adult population was available in IRIS until May 1, 1995; however, it was not listed in the IRIS update on that date. For the purposes of calculating an SV for methylmercury that is protective of fetuses and nursing infants, the EPA Office of Water has chosen to continue to use the general adult population RfD of 3×10^{-4} mg/kg/d for chronic systemic effects of methylmercury until a value is relisted in IRIS, and to reduce this value by a factor of 5 to derive an RfD of 6×10^{-5} mg/kg/d for developmental effects among infants. This factor is based on experimental results that suggest a possible fivefold increase in fetal sensitivity to methylmercury exposure. This more protective approach recommended by the EPA Office of Water was deemed to be most prudent at this time. This approach should be considered interim until such time as the Agency has reviewed new studies on the chronic and developmental effects of methylmercury.
- ^h This RfD is used in risk assessment calculations for the general adult population (see Volume II of this guidance document series [U.S. EPA, 1994]). It is not recommended that this SV be used in screening programs because it may not be protective of women of reproductive age and children.
- ⁱ The RfD for selenium is the IRIS (1992) value for selenious acid. The evidence of carcinogenicity for various selenium compounds in animal and mutagenicity studies is conflicting and difficult to interpret. However, evidence for selenium sulfide is sufficient for a B2 classification (IRIS, 1992).
- ^j The RfD and SF values listed are derived from studies using technical-grade chlordane (purity ~95%) or a 90:10 mixture of chlordane:heptachlor or analytical-grade chlordane (IRIS, 1992). No RfD or SF values are given in IRIS (1992) for the cis- and trans-chlordane isomers or the major chlordane metabolite, oxychlordane, or for the chlordane impurities cis- and trans-nonachlor. It is recommended that the total concentration of cis- and trans-chlordane, cis- and trans-nonachlor, and oxychlordane be determined for comparison with the recommended SV.
- ^k The RfD value listed is for DDT. The SF value is for DDT or DDE; the SF value for DDD is 0.24. The U.S. EPA Carcinogenicity Assessment Group recommended the use of SF = 0.34 for any combination of DDT, DDE, DDD, and dicofol (Holder, 1986). It is recommended that the total concentration of the 2,4'- and 4,4'-isomers of DDT and its metabolites, DDE and DDD, be determined for comparison with the recommended SV.
- ^l The RfD value listed is from the Office of Pesticide Program's Reference Dose Tracking Report (U.S. EPA, 1993b).
- ^m The RfD value listed is from the Office of Pesticide Program's Reference Dose Tracking Report (U.S. EPA, 1995j).

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Table 5-2 (continued)

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- ⁿ IRIS (1992) has not provided an SF for lindane. The SF value listed for lindane was calculated from the water quality criteria (0.063 µg/L) (U.S. EPA, 1992e).
- ^o The National Study of Chemical Residues in Fish (U.S. EPA, 1992c, 1992d) used a value of SF = 1.8 for mirex from HEAST (1989).
- ^p The RfD value is the Office of Pesticide Programs value; this value was never submitted for verification.
- ^q The SF value listed is for benzo[a]pyrene. Values for other PAHs are not currently available in IRIS (1995). It is recommended that, in both screening and intensive studies, tissue samples be analyzed for benzo[a]pyrene, benz[a]anthracene, benzo[b]fluoranthene, benzo[k]fluoranthene, chrysene, dibenz[a,h]anthracene, and indeno[1,2,3-cd]pyrene, and that the order-of-magnitude relative potencies given for these PAHs in the EPA provisional guidance for quantitative risk assessment of PAHs (U.S. EPA, 1993c) be used to calculate a potency equivalency concentration (PEC) for each sample for comparison with the recommended SV for benzo[a]pyrene (see Section 5.3.2.3). At this time, EPA's recommendation for risk assessment of PAHs (U.S. EPA 1993c) is considered provisional because quantitative risk assessment data are not available for all PAHs. This approach is under Agency review and over the next year will be evaluated as new health effects benchmark values are developed. Therefore, the method provided in this guidance document is subject to change pending results of the Agency's reevaluation.
- ^r The RfD for PCBs is based on the chronic toxicity of Aroclor 1254 (IRIS, 1995). This RfD is lower than the RfD that is available in IRIS (1995) for the developmental toxicity of Aroclor 1016 (7×10^{-5}) and, therefore, is protective against both chronic systemic toxicity and developmental toxicity. See Volume II (Section 5.6.19) of this guidance document series (U.S. EPA, 1994b) for a more detailed discussion of toxicity data for PCBs and their use in conducting quantitative risk assessments and determination of consumption limits.
- ^s The SF is based on a carcinogenicity assessment of Aroclor 1260. The SF of Aroclor 1260 is intended to represent the upper bound risk for all PCB mixtures (IRIS, 1992).
- ^t The SF value listed is for 2,3,7,8-tetrachlorodibenzo-p-dioxin (TCDD) (U.S. EPA, 1986c). The National Study of Chemical Residues in Fish used a value of RfD = 1×10^{-9} for 2,3,7,8-TCDD from ATSDR (1987d). It is recommended that, in both screening and intensive studies, the 17 2,3,7,8-substituted tetra- through octa-chlorinated dibenzo-p-dioxins and dibenzofurans be determined and a toxicity-weighted total concentration be calculated for each sample for comparison with the recommended SV, using the revised interim method for estimating Toxicity Equivalency Concentrations (TECs) (Barnes and Bellin, 1989; U.S. EPA, 1991h). If resources are limited, the 2,3,7,8-TCDD and 2,3,7,8-TCDF congeners should be determined at a minimum.

5. SCREENING VALUES FOR TARGET ANALYTES

Table 5-3. Example Screening Values (SVs) for Various Subpopulations and Risk Levels (RLs)^a

Chemical	Subpopulation ^b	CR ^c	BW	RfD	SF	RL	SV (ppm)
Noncarcinogens							
Chlorpyrifos	Standard adults	6.5	70	3×10^{-3}	—	—	30
	Children	6.5	36 ^d	3×10^{-3}	—	—	20
	Subsistence fishermen	140	70	3×10^{-3}	—	—	2
Cadmium	Standard adults	6.5	70	1×10^{-3}	—	—	10
	Children	6.5	36 ^d	1×10^{-3}	—	—	6
	Subsistence fishermen	140	70	1×10^{-3}	—	—	0.5
Carcinogens							
Lindane	Standard adults	6.5	70	—	1.3	10^{-4}	8×10^{-1}
					1.3	10^{-5}	8×10^{-2}
					1.3	10^{-6}	8×10^{-3}
					1.3	10^{-7}	8×10^{-4}
	Children	6.5	36 ^d	—	1.3	10^{-4}	4×10^{-1}
					1.3	10^{-5}	4×10^{-2}
					1.3	10^{-6}	4×10^{-3}
					1.3	10^{-7}	4×10^{-4}
	Subsistence fishermen	140	70	—	1.3	10^{-4}	4×10^{-2}
					1.3	10^{-5}	4×10^{-3}
					1.3	10^{-6}	4×10^{-4}
					1.3	10^{-7}	4×10^{-5}
Toxaphene	Standard adults	6.5	70	—	1.1	10^{-4}	10×10^{-1}
					1.1	10^{-5}	10×10^{-2}
					1.1	10^{-6}	10×10^{-3}
					1.1	10^{-7}	10×10^{-4}
	Children	6.5	36 ^d	—	1.1	10^{-4}	5×10^{-1}
					1.1	10^{-5}	5×10^{-2}
					1.1	10^{-6}	5×10^{-3}
					1.1	10^{-7}	5×10^{-4}
	Subsistence fishermen	140	70	—	1.1	10^{-4}	5×10^{-2}
					1.1	10^{-5}	5×10^{-3}
					1.1	10^{-6}	5×10^{-4}
					1.1	10^{-7}	5×10^{-5}

CR = Mean daily fish or shellfish consumption rate, averaged over a 70-yr lifetime for the population of concern (g/d).

BW = Mean body weight, estimated for the population of concern (kg).

RfD = Oral reference dose for noncarcinogens (mg/kg/d).

SF = Oral slope factor for carcinogens (mg/kg/d)⁻¹.

RL = Maximum acceptable risk level for carcinogens (dimensionless).

^a See Equations (5-4) and (5-5).

^b See Table 5-2 for definitions of subpopulations.

^c To calculate SVs, the CRs given in this table must be divided by 1,000 to convert g/d to kg/d.

^d BW used is for children 9 to <12 yr (see Table 5-2).

The need to accurately characterize the subpopulation of interest in order to establish sufficiently protective SVs cannot be overemphasized. For example, the recommended consumption rate of 140 g/d for subsistence fishermen may be an underestimate of consumption rate for some subsistence populations. In a recent study of Alaskan subsistence fishing economies (Wolf and Walker, 1987), daily consumption rates for subsistence fishermen were found to range from 6 to 1,536 g/d, with an average daily consumption rate of 304 g/d. Using this average consumption rate and an estimated average body weight of 70 kg, the SV for cadmium ($RfD = 1 \times 10^{-3}$ mg/kg/d) is, from Equation (5-4),

$$SV = (0.001 \text{ mg/kg/d} \cdot 70 \text{ kg}) / (0.304 \text{ kg/d}) = 0.2 \text{ mg/kg (ppm)} \quad (5-7)$$

This value is significantly lower than the SV of 0.5 ppm for cadmium based on the recommended consumption rate of 140 g/d for subsistence fishermen, as shown in Table 5-3.

5.3 COMPARISON OF TARGET ANALYTE CONCENTRATIONS WITH SCREENING VALUES

As noted previously, the same SV for a specific target analyte should be used in both the screening and intensive studies. The measured concentrations of target analytes in fish or shellfish tissue should be compared with their respective SVs in both screening and intensive studies to determine the need for additional monitoring and risk assessment.

Recommended procedures for comparing target analyte concentrations with SVs are provided below. Related guidance on data analysis is given in Section 9.1.

5.3.1 Metals

5.3.1.1 Arsenic—

Most of the arsenic present in fish and shellfish tissue is organic arsenic, primarily pentavalent arsenobetaine, which has been shown in numerous studies to be metabolically inert and nontoxic (Brown et al., 1990; Cannon et al., 1983; Charbonneau et al., 1978; Jongen et al., 1985; Kaise et al. 1985; Luten et al., 1982; Sabbioni et al., 1991; Siewicki, 1981; Tam et al., 1982; Vahter et al., 1983; Yamauchi et al., 1986). Inorganic arsenic, which is of concern for human health effects (ATSDR, 1993; WHO, 1989), is generally found in seafood at concentrations ranging from <1 to 20 percent of the total arsenic concentration (Edmonds and Francesconi, 1993; Nraigu and Simmons, 1990). It is recommended that, in both screening and intensive studies, total inorganic arsenic tissue concentrations be determined for comparison with the recommended SV for chronic oral exposure. This approach is more rigorous than the current FDA method of analyzing for total arsenic and estimating inorganic arsenic concentrations based on the assumption that 10 percent of the total arsenic in fish tissue is in the inorganic form (U.S. FDA, 1993). Although the cost of analysis for inorganic arsenic (see Table 8-5) may be three to five times greater than for total

arsenic, the increased cost is justified to ensure that the most accurate data are obtained for quantitative assessment of human health risks.

5.3.1.2 Cadmium, Mercury, and Selenium—

For cadmium, mercury, and selenium, the total metal tissue concentration should be determined for comparison with the appropriate SV. For mercury, the SV that is calculated from the RfD for developmental effects of methylmercury (see Table 5-2) should be used because it is most protective.

The determination of methylmercury is not recommended even though methylmercury is the compound of greatest concern for human health (NAS, 1991; Tollefson, 1989) and the recommended SV is for methylmercury (see Table 5-2). Because most mercury in fish and shellfish tissue is present as methylmercury (NAS, 1991; Tollefson, 1989), and because of the relatively high analytical cost for methylmercury, it is recommended that total mercury be determined and the conservative assumption be made that all mercury is present as methylmercury. This approach is deemed to be most protective of human health and most cost-effective.

Note: The EPA has recently reevaluated the RfD for methylmercury, primarily because of concern about evidence that the fetus is at increased risk of adverse neurological effects from exposure to methylmercury (Marsh et al., 1987; Piotrowski and Inskip, 1981; NAS, 1991; WHO, 1976, 1990). On May 1, 1995, IRIS was updated to include an oral RfD of 1×10^{-4} mg/kg/d based on developmental neurological effects in human infants. An oral RfD of 3×10^{-4} mg/kg/d for chronic systemic effects of methylmercury among the general adult population was available in IRIS until May 1, 1995; however, it was not listed in the IRIS update on that date. For the purposes of calculating an SV for methylmercury that is protective of fetuses and nursing infants, the EPA Office of Water has chosen to continue to use the general adult population RfD of 3×10^{-4} mg/kg/d for chronic systemic effects of methylmercury until a value is relisted in IRIS, and to reduce this value by a factor of 5 to derive an RfD of 6×10^{-5} mg/kg/d for developmental effects among infants. This factor is based on experimental results that suggest a possible fivefold increase in fetal sensitivity to methylmercury exposure. This more protective approach recommended by the EPA Office of Water was deemed to be most prudent at this time. This approach should be considered interim until such time as the Agency has reviewed new studies on the chronic and developmental effects of methylmercury.

5.3.1.3 Tributyltin—

Tissue samples should be analyzed specifically for tributyltin for comparison with the recommended SV for this compound.

5.3.2 Organics

For each of the recommended organic target analytes that are single compounds, the determination of tissue concentration and comparison with the appropriate SV is straightforward. However, for those organic target analytes that include a parent compound and structurally similar compounds or metabolites (i.e., total chlordane, total DDT), or that represent classes of compounds (i.e., PAHs, PCBs, dioxins/furans), additional guidance is necessary to ensure that a consistent approach is used to determine appropriate target analyte concentrations for comparison with recommended SVs.

5.3.2.1 Chlordane—

The SV for total chlordane is derived from technical-grade chlordane. Oral slope factors are not available in IRIS (1992) for cis- and trans-chlordane, cis- and trans-nonachlor, and oxychlordane. At this time, as a conservative approach, EPA recommends that, in both screening and intensive studies, the concentrations of cis- and trans-chlordane, cis- and trans-nonachlor, and oxychlordane be determined and summed to give a total chlordane concentration for comparison with the recommended SV for total chlordane (see Table 5-2).

5.3.2.2 DDT—

DDT and its metabolites (i.e., the 4,4'- and 2,4'-isomers of DDE and DDD) are all potent toxicants, DDE isomers being the most prevalent in the environment. As a conservative approach, EPA recommends that, in both screening and intensive studies, the concentrations of 4,4'- and 2,4'-DDT and their DDE and DDD metabolites be determined and a total DDT concentration be calculated for comparison with the recommended SV for total DDT (see Table 5-2).

5.3.2.3 PAHs—

Although several PAHs have been classified as B2 carcinogens (probable human carcinogens), benzo[a]pyrene is the only PAH for which an SF is currently available in IRIS (1995). As a result, EPA quantitative risk estimates for PAH mixtures have often assumed that all carcinogenic PAHs are equipotent to benzo[a]pyrene. The EPA Office of Health and Environmental Assessment has recently issued provisional guidance for quantitative risk assessment of PAHs (U.S. EPA, 1993c) in which an estimated order of potential potency for six Group B2 PAHs relative to benzo[a]pyrene is recommended, as shown in Table 5-4. Based on this guidance, it is recommended that, in both screening and intensive studies, tissue samples be analyzed for the seven PAHs shown in Table 5-4 and that a potency-weighted total concentration be calculated for each sample for comparison with the recommended SV for benzo[a]pyrene. This potency equivalency concentration (PEC) should be calculated using the following equation:

$$PEC = \sum_i (RP_i \cdot C_i) \quad (5-8)$$

where

RP_i = Relative potency for the i th PAH (from Table 5-4)

C_i = Concentration of the i th PAH.

At this time, EPA's recommendation for risk assessment of PAHs (U.S. EPA, 1993c) is considered provisional because quantitative risk assessment data are not available for all PAHs. This approach is under Agency review and over the next year will be evaluated as new health effects benchmark values are developed. Therefore, the method provided in this guidance document is subject to change pending results of the Agency's reevaluation.

5.3.2.4 PCBs—

Using the interim approach for PCB analysis recommended by the EPA Office of Water (see Section 4.3.5), total PCB concentrations should be determined, in both screening and intensive studies, as the sum of Aroclor equivalents. The total PCB concentration should be compared with the recommended SV for PCBs (see Table 5-2). Because this SV is based on the SF for Aroclor 1260, the recommendation to use this SV for comparison with total Aroclor concentration requires the assumption that Aroclor 1260 is representative of

Table 5-4. Estimated Order of Potential Potencies of Selected PAHs

Compound	Relative Potency ^{a,b}	Reference
Benzo[<i>a</i>]pyrene	1.0	
Benz[<i>a</i>]anthracene	0.1	Bingham and Falk, 1969
Benzo[<i>b</i>]fluoranthene	0.1	Habs et al., 1980
Benzo[<i>k</i>]fluoranthene	0.01	Habs et al., 1980
Chrysene	0.001	Wynder and Hoffmann, 1959
Dibenz[<i>a,h</i>]anthracene	1.0	Wynder and Hoffmann, 1959
Indeno[1,2,3- <i>cd</i>]pyrene	0.1	Habs et al., 1980; Hoffmann and Wynder, 1966

^a Model was $P(d)=1-\exp[-a(1+bd)^2]$ for all but indeno[1,2,3-*cd*]pyrene.

^b Values listed are order-of-magnitude potencies based on the following scheme for rounding experimental values: 0.51–5.0=1.0; 0.051–0.50=0.1; 0.0051–0.050=0.01.

Source: Modified from U.S. EPA, 1993c.

other PCB mixtures, i.e., that the SF for Aroclor 1260 is an upper limit risk estimate for all other PCB mixtures as well (IRIS, 1992; U.S. EPA, 1988a). The EPA Office of Water recognizes that this assumption has significant uncertainties.

The comparison of total PCB concentrations (determined as the sum of Aroclor equivalents) with the Aroclor 1260-based SV may be overly conservative. The EPA Carcinogen Assessment Group has reported a much lower SF for Aroclor 1254 (SF = 2.6) and data from studies of Aroclor 1242 (Schaeffer et al., 1984) indicate that there are no statistically significant increases in liver tumors compared to controls. A recent reassessment of the results of five PCB studies in rats found significant differences between Aroclor 1260 and other Aroclors in the types and incidence of pathological effects on rats (IEHR, 1991). On the other hand, Aroclor 1260 may not represent an upper bound risk estimate because the PCB congener distribution in fish and shellfish tissue is usually markedly altered from, and may be more potent than, the parent Aroclor mixture (Bryan et al., 1987; Kubiak et al., 1989; Norstrom, 1988; Oliver and Niimi, 1988; Smith et al., 1990). This underscores the need to move toward congener-specific analysis based on (1) pharmacokinetics and (2) relative potency at specific site(s) of action (NAS, 1991).

EPA also recognizes that the current recommended SV of 10 ppb for total PCBs will result in widespread exceedance in waterbodies throughout the country and will drive virtually all fish and shellfish contaminant monitoring programs into the risk assessment phase for PCBs. The decision on whether to issue a consumption advisory for PCBs at this level is one that must be made by risk managers in each State.

EPA is currently giving high priority to addressing the unresolved issues related to PCB analysis and risk assessment. A work group has been convened to examine the feasibility of TEFs for PCB congeners similar to those developed for PCDDs and PCDFs (U.S. EPA, 1991j) and two EPA-sponsored national workshops have been held recently to identify problematic issues and areas for future research (U.S. EPA, 1993d; U.S. EPA, 1993e). Additional guidance on PCB analyses will be provided in addenda to this document and in subsequent documents in this series.

5.3.2.4 Dioxins and Dibenzofurans—

Note: At this time, the EPA Office of Research and Development is reevaluating the potency of dioxins/furans. Consequently, the following recommendation is subject to change pending the results of this reevaluation.

It is recommended in both screening and intensive studies that the 17 2,3,7,8-substituted tetra- through octa-chlorinated PCDDs and PCDFs be determined and that a toxicity-weighted total concentration be calculated for each sample for comparison with the recommended SV for 2,3,7,8-TCDD (see Table 5-2).

5. SCREENING VALUES FOR TARGET ANALYTES

The revised interim method for estimating toxicity equivalency concentrations (Barnes and Bellin, 1989) should be used to estimate TCDD equivalent concentrations according to the following equation:

$$TEC = \sum_i (TEF_i \cdot C_i) \quad (5-9)$$

where

TEF_i = Toxicity equivalency factor for the i th congener (relative to 2,3,7,8-TCDD)

C_i = Concentration of the i th congener.

TEFs for the 2,3,7,8-substituted tetra- through octa-PCDDs and PCDFs are shown in Table 5-5.

If resources are limited, the 2,3,7,8-TCDD and 2,3,7,8-TCDF congeners should be determined and the calculated TEC compared with the recommended SV for 2,3,7,8-TCDD (see Table 5-2).

Table 5-5. Toxicity Equivalency Factors (TEFs) for Tetra-through Octa-Chlorinated Dibenzo-p-Dioxins and Dibenzofurans

Analyte	TEF^a
2,3,7,8-TCDD	1.00
1,2,3,7,8-PeCDD	0.50
1,2,3,4,7,8-HxCDD	0.10
1,2,3,6,7,8-HxCDD	0.10
1,2,3,7,8,9-HxCDD	0.10
1,2,3,4,6,7,8-HpCDD	0.01
OCDD	0.001
2,3,7,8-TCDF	0.10
1,2,3,7,8-PeCDF	0.05
2,3,4,7,8-PeCDF	0.50
1,2,3,4,7,8-HxCDF	0.10
1,2,3,6,7,8-HxCDF	0.10
1,2,3,7,8,9-HxCDF	0.10
2,3,4,6,7,8-HxCDF	0.10
1,2,3,4,6,7,8-HpCDF	0.01
1,2,3,4,7,8,9-HpCDF	0.01
OCDF	0.001

Source: Barnes and Bellin, 1989.

^aTEFs for all non-2,3,7,8-substituted congeners are zero.